

REMARKS

Claims 1-27 are pending in the subject application. Claims 10-27 have been withdrawn for being directed to a non-elected invention and claim 9 has been canceled without prejudice. Therefore, following entry of the amendments claims 1-8 will be pending and under examination. Claim 1 has been amended. Support for the amendment can be found throughout the application as filed. In particular, support for the amendment reciting that the stoichiometric matrix includes the exchange flux reactions can be found at, for example, page 15, lines 4-21 and page 17, lines 19-22. Therefore, the amendments do not raise an issue of new matter and entry thereof is respectfully requested.

Applicants have reviewed the rejections set forth in the Office Action mailed August 12, 2005, and respectfully traverse all grounds for the reasons that follow.

Rejections Under 35 U.S.C. § 101

Claims 1-7 stand rejected under 35 U.S.C. § 101 allegedly for being non-statutory subject matter. The Office alleges that the claimed method of analyzing the production of a metabolite lacks specificity as to what types of compounds are generated and therefore fails to produce a concrete, tangible and useful result.

As pointed out in the Office Action, *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, is the applicable law for determining whether a computer related algorithm or data structure is statutory subject matter. *State Street* held that a computer algorithm having a practicable application is statutorily patentable where it produces a concrete, useful and tangible result. *Id.*, 149 F. 3d 1368, 1373-74 (Fed. Cir. 1998).

The claimed invention is directed to a method of analyzing the production of one or more selected metabolites of a biochemical reaction network. The method includes determining reaction sets which, when stopped, affect the capability of the network to produce the output metabolite of interest. Applicants submit that the process of determining reaction sets that affect the output of a metabolite of interest is a practical application having a concrete, useful and tangible result because the method and the result can be used to produce biochemical products of

interest. The result also identifies a point of interdiction that can be targeted for a variety of therapeutic purposes as described, for example, at page 14, lines 14-32.

For example, the application describes that the methods of the invention can be used to re-engineer a cell to produce a desired product and/or to improve the production of bio-commodities when it teaches:

[O]nce it is understood what a biochemical reaction network is doing, and how it is doing it, then it may become possible to "re-engineer" the network, and the organism, to steer more of its output into desired channels (i.e., to make more of a desired reaction product).

[T]he same mathematical computational tools can be used to improve the design and engineering of organisms for industrial application such as the production of bio-commodities. The tools permit recognition of how an beneficial process and pathway of the biochemical reaction network might be augmented or accentuated.

Application at page 3, line 22 through page 4, line 5.

The production of a biochemical product and/or a bio-commodity including, for example, a protein or metabolite has a broad range of uses for therapeutic treatments, nutrition and other commercial applications. For example, enhanced production of a protein is particularly useful for production of a therapeutic for treatment of a disease. Similarly, enhanced production of a metabolite also is particularly useful for production of a nutritional product. Therefore, predicting a design for re-engineering an organism to produce or augment the production of these biochemical products yields a concrete, useful and tangible result having practical application. Accordingly, the claimed methods of the invention are statutory patentable and withdrawal of this ground of rejection is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 1-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite allegedly because the phrase "in consideration of the exchange fluxes" is unclear. The Office

questions whether the stoichiometric matrix contains representations of the exchange fluxes and requests clarification.

Applicants submit that the phrase is clear as written. However, to further prosecution, claim 1 has been amended to recite that the stoichiometric matrix includes the exchange flux reactions. In light of this amendment, this ground of rejection is moot and its withdrawal is respectfully requested.

Claim 9 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. The Office alleges that claim 9, directed to a drug developed using a reaction set of the invention to target development of a drug, but that the specification fails to describe any steps of developing or synthesizing a drug.

Applicants submit that the application sufficiently describes the claimed invention to show that they were in possession of the claimed invention at the time the application was filed. Nevertheless, to further prosecution of this application, claim 9 has been canceled without prejudice. Applicants reserve the right to pursue this claim in a later filed application claiming the benefit of priority to the above identified application. In light of this amendment, this ground of rejection is moot and its withdrawal is respectfully requested.

Prior Art Rejections

Claims 1-9 stand rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Schilling et al. (2001) and claim 9 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over Schilling et al. (2001). Applicants respectfully submit that these grounds of rejection have been rendered moot by the Katz-type Rule 132 Declaration of Drs. Schilling and Letscher, submitted herewith, establishing that the cited reference describes Applicants' own work. Moreover, claim 9 has been canceled. Accordingly, the Schilling et al. (2001) reference is not applicable as prior art. Reconsideration and withdrawal of this ground of rejection is respectfully requested.

In re Application of:
Schilling and Letscher
Application No.: 09/928,191
Filed: August 11, 2001
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PATENT
Attorney Docket No.: UCSD1680

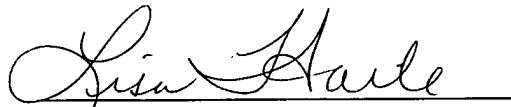
CONCLUSION

In summary, for the reasons set forth herein, Applicants respectfully submit that claims 1-8 clearly and patentably define the invention and allowance of the claims is respectfully requested. If the Examiner would like to discuss any issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Enclosed is Check No. 580846 in the amount of \$510.00 as payment for a Three Month Extension of Time fee. No additional fees are believed due with the present response. However, if a fee is required, the Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

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